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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/925,326	09/08/97	LEBAUT	G 24124996/09 ^{mk}

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EXAMINER

OSWECKI, J

ART UNIT

PAPER NUMBER

1613

12

DATE MAILED: 03/17/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/925,326

Applicant(s)
Lebaut et al.

Examiner
Jane Oswecki

Group Art Unit
1613



☒ Responsive to communication(s) filed on February 16, 1999 in Paper No. 11

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 2 and 5-14 is/are pending in the application.

Of the above, claim(s) 8 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2, 5-7, and 9-14 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 2, 5-7 and 9-14 are pending in the application. Claims 1, 3 and 4 have been canceled by amendment. Claim 8 remains withdrawn from consideration according to the Restriction Requirement of Paper No. 7 and subsequent election of Group II in Paper No. 8. Claims 9-14 have been added by amendment. All cited references have been considered and any cited but not applied are cited to show the state of the art. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 2, 5-7 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. 3,801,594 to Poletto et al.

The applicants claim optionally substituted indol-3-glyoxylamide derivative compounds having pyridyl or quinolyl as a substituent in the R₁ position. These compounds have utility as immunodilator and anti-asthmatic agents.

Poletto et al. teach optionally substituted heteroethyleneindole derivative compounds which have utility as central nervous system depressants, analgesics, diuretics and anti-inflammatories (U.S. Pat. 3,801,594, Abstract). Poletto et al. further teach optionally substituted 5-methoxyindole-3-glyoxylamide derivative compounds that may have an "R₁" substituent that is pyridinyl or quinolyl (U.S. Pat. 3,801,594 at column 8, Table II, lines 10-63 and especially lines 10-20 and 46-49).

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The difference between the compounds of the instant application and those taught by Poletto et al. is that Poletto et al. teach a methyl substituent at position-2 on the indole moiety of the compound and only oxygen atoms at positions comparable to the instant "Z" substituents (U.S. 3,801,594 at col. 8, Table II, lines 10-64).

Thus, it would have been obvious to one skilled in the art of glyoxylamide derivative compounds to have utilized the optional substituents as taught by Poletto et al. on the indolyl-3-glyoxylamide derivative compounds having a pyridyl or quinolyl substituent also as taught by Poletto et al. A skilled artisan would have been motivated to do so in order to prepare additional anti-asthmatic and immunodilatory compounds.

Claim Objections

Claims 2, 9, 10 and 12-14 are objected to because of the following informalities: each of these claims includes subject matter that is non-elected according to the Restriction Requirement of Paper No. 7 and election in Paper No. 8. Thus, claim 2 at page 32, lines 1-11 and 15-16 require deletion; claim 9 at page 3, part (3), pyrimidinyl and, for R₁ and R together, piperazine, structure (III) and homopiperazine require deletion; claim 10 at page 5 requires deletion of histidyl and prolyl in addition to any amino acid radicals containing heterocyclic substituents other than 6-membered rings having one nitrogen and 5 carbon atoms; claim 12 at page 6 requires amendment of the definition of R₁ which embraces all amino acids; and claims 13 and 14 require the same amendments as for claim 9. Appropriate correction is required in these and all other occurrences.

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Response to Amendments

Applicants' amendments filed February 16, 1999 in Paper No. 11 are sufficient to overcome the rejection of claims 3 and 4 under 35 U.S.C. 101; the rejection of claims 1 and 2 under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over Evans et al., "Probing the 5-HT₃ receptor site using novel indole-3-glyoxylic acid derivatives," Med. Chem. Res., 3(5-6), 1993, pp. 386-406; the rejection of claims 1, 5 and 6 under 35 U.S.C. 112, first paragraph; the rejection of claims 1, 5 and 6 under 35 U.S.C. 112, second paragraph; and the objections to claims 1, 6 and 7.

However, applicants' amendments are found insufficient to overcome the rejection of claim 2 under 35 U.S.C. 103 (a) over U.S. Pat. 3,801,594 to Poletto et al.

Response to Arguments

Applicants' arguments filed February 16, 1999 in Paper No. 11 have been fully considered and are deemed persuasive to overcome the rejection of claims 3 and 4 under 35 U.S.C. 101; the rejection of claims 1 and 2 under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over Evans et al., "Probing the 5-HT₃ receptor site using novel indole-3-glyoxylic acid derivatives," Med. Chem. Res., 3(5-6), 1993, pp. 386-406; the rejection of claims 1, 5 and 6 under 35 U.S.C. 112, first paragraph; the rejection of claims 1, 5 and 6 under 35 U.S.C. 112, second paragraph; and the objections to claims 1, 6 and 7.

Applicants' arguments are found unpersuasive to overcome the rejection of claim 2 under 35 U.S.C. 103(a) over U.S. Pat. 3,801,594 to Poletto et al. The applicants argue that the 3-glyoxylic groups taught by Poletto et al. are not amides in the intermediate compounds, and that

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the variety of activities taught by Poletto et al. differ from those activities of the instant application. However, the compound Nos. 19-33 prepared by Poletto et al. and found in Table II are clearly labeled as "2, (4, 6 or 7)-dimethyl-5-methoxyindole-3-glyoxylamides" whether used as intermediates or final products (U.S. Pat. 3,801,594 at col. 8, lines 10-65). Further, applicants are correct that Poletto et al. teach anti-depressant, anti-inflammatory, analgesic, tranquilizing and diuretic utilities for their compounds (U.S. Pat. 3,801,594 at col. 1, Abstract). However, applicants claim that the compounds of the instant application have utility as "medicaments". It is difficult to detect a difference between the instantly claimed and prior art utilities except that the term "medicaments" embraces a broader scope of pharmaceutical agents.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

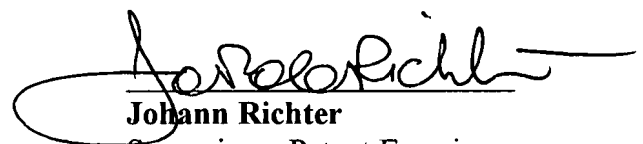
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Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Oswecki whose telephone number is (703)305-7152. The examiner can normally be reached Monday through Thursday from 7:30 AM to 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at (703)308-4532. The telephone number for this Group is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-1235.


Johann Richter
Supervisory Patent Examiner
Group 1600

JCO
March 11, 1999